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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 978,486	10 15 2001	Yi-Jyun Lin	06618-343002	5129

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EXAMINER

ANDRES, JANET L.

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 01 07 2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,486

Applicant(s)

LIN ET AL.

Examiner

Janet L Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. ____.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a prior national application).

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement (PCT/144) (if applicable)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)

Art Unit: 1646

DETAILED ACTION

Priority

1. Applicant's priority claim to 60/095826 and 09/370098, now U.S. patent 6303768, is acknowledged.

Specification

2. The disclosure is objected to because of the following informalities: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The reference to U.S. patent 6303768 is missing.

There is a sequence on p. 79 that lacks a sequence identifier.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to antibodies and, in claim 4, "mth binding reagents" that interact with

Art Unit: 1646

polypeptides". The specification sets forth no required characteristics for these molecules; Applicant describes SEQ ID NO: 2 as "exemplary" on p. 22 but does not indicate what features it possesses that are characteristic of "mth polypeptides". There is no defining activity for "mth polypeptides" the specification provides only examples on pages 23 and 23. Thus there is no description of the structural and functional features of mth polypeptides, or of the conserved regions that would be critical for these features. Since these features are not disclosed, there is no way to determine what other molecules possess the same defining characteristics. Further, the art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polypeptides encompassed, and thus to identify antibodies directed against the polypeptides. Zou et al. (Proc. Nat. Acad. Sci. 2000, vol. 97, pp. 13726-13731) teaches that the factors that affect aging and stress resistance in drosophila are varied. The indication that methuselah is a G-protein coupled receptor is also not sufficient to allow one of skill to identify other mth polypeptides. Hamm (J. Biol. Chem., 1998, vol. 278, pages 669-672), for example, teaches that more than a thousand such receptors are known. Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that Applicant was in possession of the genus of mth polypeptides, and thus of the claimed genus of antibodies against them. Claim 4 additionally encompasses "binding reagents". However, no binding reagents other than antibodies are provided by the specification. Applicant has described no features required for mth binding and no other characteristics of such molecules. Thus one of skill in the art would not conclude that Applicant was in possession of

Art Unit: 1646

5. Claims 4-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies against SEQ ID NO:2, does not reasonably provide enablement for all reagents binding to all mth polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As stated above, Applicant has not described the characteristics of mth polypeptides so that one of skill in the art could predictably identify other such polypeptides, nor has Applicant described any identifying characteristics of reagents, other than antibodies specific for SEQ ID NO: 2, that would bind with such proteins. Applicant has not described the properties or characteristics of the sequences that are required for a functional mth polypeptide. Thus, the essential characteristics such proteins are not described. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features are characteristic of mth polypeptides, in order to generate antibodies that would predictable react with all such polypeptides. Additionally, since no identifying characteristics for binding reagents other than antibodies are set forth in the specification, one of skill in the art would not be able to predict what reagents, if any, other than antibodies would react with mth polypeptides and could thus be used as claimed. Therefore, since the characteristics that identify "binding reagents" other than antibodies and "mth

Art Unit: 1646

insufficient guidance to allow one of skill in the art to predictably make and use the invention as broadly claimed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite in the recitation of "binding". There is no indication that the binding need be specific, and no limitation on the degree of interaction that would be considered as "binding". Thus one of skill in the art would not be able to determine what molecules were encompassed by the claims.

Claim 4 is indefinite in the recitation of an "mth binding reagent". There is no definition of such reagents in the specification, no requirement that the binding be specific, and no definition of what degree of interaction would be considered to be "binding". Thus one of skill in the art would not be able to determine what molecules were encompassed by the claim.

Claims 4-8 are indefinite in the recitation of "an mth polypeptide". There is no definition of such polypeptides in the specification. What is provided on p. 22-23 are one example, SEQ ID NO: 2, and examples of activities such polypeptides might have. Thus one of skill in the art would not be able to determine what polypeptides would be considered to be "mth polypeptides".

NO CLAIMS ALLOWED

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
December 31, 2001

YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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